Original Research

Case-control study of 10 years of comprehensive diabetes care

ABSTRACT ● **Objective** To describe the long-term clinical impact of a comprehensive management program instituted throughout a health system for members with diabetes mellitus. ● **Design** 10 year case-control evaluation. ● **Setting** Kaiser Permanente Northwest, Portland, OR. ● **Participants** Members of the health maintenance organization between 1987 and 1996; members with diabetes were compared with equal numbers of members without diabetes. The number of participants with diabetes ranged from 5331 in 1987 to 13,099 in 1996. ● **Main outcome measures** Number in diabetes register, mortality, change in comorbidity, rates of uptake of preventive health measures, use of pharmaceuticals, levels of risk factors, hospital days per thousand per year, emergency room visits per thousand per year. ● **Results** The prevalence of diabetes identified in this population rose from 2.54% (7,895/310,819) in 1987 to 3.66% (14,741/402,754) in 1996, and the mean (SEM) age of members at the time of diagnosis fell slightly from 62.9 (±0.21) years to 62.0 (±0.13) years ($P < 0.05$). By 1996, 10,885 of the 13,099 (83% ±0.3%) of members with diabetes had an annual laboratory test to assess glycemic control, the annual screening rate for retinopathy was 67.6% (±0.4%), the rate of uptake of influenza immunizations was 60.2% (7,886/13,099) and the screening rate for nephropathy was 43% (5,698/13,099) (±0.49%). The use of home glucose testing increased from 32.4% (1721/5331) of members with diabetes to 53.0% (6,942/12,099); the use of lipid lowering drugs increased from 3.5% (187/55,331) to 19.8% (2,594/13,099). The use of angiotensin converting enzyme inhibitors increased from 8.5% to 34.8% of members with diabetes. Mean blood pressure decreased from 144/82 mm Hg (±0.8/0.4) to 138/79 mm Hg (±0.3/0.15), and mean total cholesterol concentrations dropped from 243 mg/dL (±4.2) to 215 mg/dL (±0.6). By 1996, 56.4% (7,388/1,3099) (±0.5%) of members on the diabetes register had good to excellent glycemic control (HbA_{1c} <8%). Mortality decreased from 4.8% (256/5331) (±0.3%) to 3.6% (472/13,099) (±0.2%) among members with diabetes, this was a more rapid decrease than was observed among those without diabetes ($P < 0.01$). The annual ratio of visits to the emergency room by members with diabetes to members without fell from 2.5 to 1.8, and the ratio for the number of days spent in acute care in the hospital dropped from 3.6 to 2.5. ● **Conclusions** This centrally organized program based in a primary care setting and utilizing a register of patients with diabetes was associated with substantial improvements in the process and outcomes of care in a large population of health maintenance organization members with diabetes.

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Over the past decade, prospective randomized trials have shown that intensive treatment can reduce the development and progression of many of the complications of diabetes mellitus.[1-7] These trials studied risk factors separately, usually within homogeneous groups of highly selected and motivated participants. The studies were not designed to measure population-based impact, did not study typical populations in routine settings of care, and did not assess the effects of the management of diabetes throughout a health system. Moreover, they did not attempt to assess the impact of real life changes in treatment guidelines in the complex, interactive systems that make up the social and economic environments of medical care.

Several reports of real world efforts to reorganize diabetes care have now appeared but these studies have been of uncertain generalizability because of limited scope and/or short duration.[8-19] We do not yet have data on the effects of such efforts on long-term complications, mortality, and net long-term changes in resource use.

METHODS

Study site and population

The study site was the northwest region of the Kaiser Permanente medical care program, a non-profit, health maintenance organization located in Portland, Oregon, and the surrounding metropolitan area. Members of the organization are similar in terms of age, economic status, and education to residents in the surrounding community, who are largely non-Hispanic white people. Membership grew from about 340,000 to about 400,000 people during the study. The study site is extensively described elsewhere.[20-24]

Intervention

In 1988, the organization began a program of population-based primary care management of diabetes. Up until 1995, this program had evolved to include an electronic diabetes register (begun in 1987) that has been updated weekly since 1993 and that supports most of the organi-

Summary points

- Over the past decade, prospective randomized trials have shown that intensive treatment can reduce the development and progression of many of the complications of diabetes mellitus
- Several reports of real world efforts to reorganize diabetes care have been of short duration and uncertain generalizability
- In 1988, our health maintenance organization began a program of population-based primary care management of diabetes
- By 1996, mortality had decreased among members with diabetes, and the annual ratio of visits to the emergency room by members with diabetes to members without fell from 2.5 to 1.8
- This centrally organized program was associated with substantial improvements in the process and outcomes of care in a large population of members with diabetes

zation's other diabetes programs; a diabetes steering committee, consisting of endocrinologists, primary care physicians, nurse managers, pharmacists, a health plan administrator, a data analyst, and a researcher; a program of diabetes research in the affiliated research center that created the register and extensively evaluated diabetes care in 1990; annual educational updates for providers affiliated with the health plan and, since 1991, the publication of a quarterly newsletter for health plan clinicians. For patients the program has developed improved patient education plans which offer better access to diabetes classes (since 1993); a restructured curriculum that teaches patients how to reduce their risk of cardiovascular disease as well as antihyperglycemic care; the introduction of diabetes educators into primary care medical offices (1992-1995); and a shift to a teaching focus that is more modular, less didactic, and more oriented towards patient empowerment; population-based management by nurses using behavioral and medical protocols in the patient empowerment framework; support of patients by pharmacists, which includes training in self-monitoring of glucose concentrations, counseling at the time of the first purchase of new drug treatment, feedback to physicians about the patient's ordering of drug treatment, and providing assistance to the nurse care managers; group sessions led by nurses[15]; cooperative care clinics (group medical visits for people with diabetes) used by some physicians starting in 1994; outreach programs for flu immunization and screening for retinopathy; electronic flagging of the charts of outpatients and people hospitalized with diabetes to alert staff and to drive programs such as automatic shoe removal and foot checking (started in 1994); guideline development and implementation for type 2 diabetes starting in 1993 (including a closely followed 1995 recommendation to use metformin in cases of secondary sulfonylurea failure); and quarterly reports to primary care clinicians about the status of their panels of patients with diabetes (since 1995) with regular population tracking reports to the diabetes steering committee (since 1993).

Analytic methods

Our primary analytic objectives were to provide a benchmark against which data from diabetes management programs could be compared as they became available and to show the direction, if not the exact magnitude, of the long-term impact of the organization's diabetes management program. The program was a natural experiment affecting a growing and changing population of patients in a medical care environment that also evolved to include other, similar initiatives. Our approach was primarily descriptive to provide maximum transparency and useful reports. Our objectives were to provide as much data as possible about the changing composition of the register as well as about its outcomes and to show a complete chain of improvement.

In addition, when data were available, we used a case-control method. To control for evolution in the composition of the register and for secular changes in market forces, organizational structure, and processes of care, members without diabetes were matched annually to members with diabetes on a one to one basis by age, gender, duration of membership in the health plan, and level of pharmacy benefits. We then calculated ratios of utilization and mortality in members with diabetes and compared these with the ratios in members without diabetes to track changes in the status of members with diabetes. The ratios provide standardized indexes by which change in diabetes-specific performance can be observed. If, for example, the ratio of the annual number of days spent in hospital by members with diabetes as compared with those without diabetes drops, it is reasonable to conclude that something specific to the care of diabetes or to the health of those on the diabetes register reduced the use of hospital resources.

To test the hypothesis that mortality improved more quickly in people with diabetes than in those without, we regressed mortality ratios against time. For most outcomes, however, changes over time were clearly clinically and statistically significant, obviating statistical modeling. We present many of our results graphically. (These results can be found on the *WJM*'s website.) Standard errors for mean values and P values for differences between starting and ending values are presented. Statistical analyses were performed using SAS software version 6.12 (SAS Institute, Cary, NC).

Sources of data and definition of measures

Members with diabetes were identified for the register from dispensing records for insulin, sulfonylurea drugs,

metformin, and blood glucose testing supplies[21]; from hospital discharge diagnoses reflecting the presence of diabetes; and from diabetes education contacts. An endocrinologist (HSG) reviewed uncertain cases weekly, including registrants identified solely from the purchase of testing supplies. Since inception, the register has been more than 99% specific for diagnosed diabetes, based on comparisons with 425 randomly selected medical charts. In 1987, we estimated that the register was 85%-90% sensitive for diagnosed diabetes, based on comparisons against laser photocoagulation records and other data. By 1994, based on a comparison with electronic records of HbA_{1c} results, we found the register to be more than 99% sensitive.

Data describing diabetes registrants were obtained from the organization's electronic clinical and management records. These include records of all acute hospitalizations (since 1975), all prescriptions dispensed from pharmacies (since 1986), all ambulatory care appointments (since 1986), all clinical services purchased outside of the organization (since 1986), and all clinical laboratory testing on members (since mid-1993). Laboratory data for 1987 and 1988 were abstracted from the paper medical records of 425 randomly selected registrants. Hospital data include admissions to acute care hospitals both within the organization and outside it.

To provide a valid denominator for annually defined performance measures, we included any registrant's data only for years when she or he belonged to the organization for 12 full months. Laboratory values are the average of all values for the relevant calendar year. We defined nephropathy screening as measurement of either urinary albumin concentration on a random or 24-hour timed specimen or a timed collection for total urinary protein. We defined hyperlipidemia screening and tracking as any total cholesterol or fasting lipid test. Between 1994 and 1997, the most common test for chronic hyperglycemia monitoring in the organization was the fructosamine assay. In this report, we convert fructosamine results to their HbA_{1c} equivalents (using the Diamat HPLC assay) using the formula: fructosamine concentration/40 = HbA_{1c}. This approximates the actual relationship found in our population and is based on the regression analysis of 364 paired samples drawn simultaneously (S Welch, unpublished data). To measure comorbidity at the time of diagnosis, we calculated the Chronic Disease Score, a validated measure that estimates the number and severity of chronic health conditions for an individual based on data describing his or her purchases of drugs.[25,26]

We presumed that an annual retinal screening occurred whenever a registrant had one or more visits to an optometrist or ophthalmologist at the organization in one calendar year. We defined mortality as the probability that a person included in the analysis in a given year died in the following year. (Because people who die cannot have 12 full months of eligibility in the year they die, we cannot report mortality in the year of observation and also maintain comparability with other data in this report.) Mortality was ascertained from records of health plan membership.

RESULTS

Register composition and growth

The number of people on the register grew linearly, more than doubling during the 9 years from 5339 people registered on January 1, 1987, to 13,099 registered by January 1, 1996, as new diagnoses and new enrollments exceeded deaths and disenrollment from the health plan. The number of newly diagnosed and newly enrolled members with diabetes was nearly constant each year, except for a modest spike in new members with pre-existing diabetes in 1996, when enrollment in the organization increased substantially. The number of deaths remained roughly proportional to the number registered, and the rate of disenrollment grew slightly. As a result, the overall prevalence of diabetes diagnosed in the organization's membership grew from 254/10,000 in 1987 to 360/10,000 in 1996 (see figure 1 on the *WJM*'s website).

Aging and mortality

The mean age of registrants decreased only slightly over the 10 years from 62.9 (SE 0.21) years to 62.0 (0.13) years ($P < 0.05$). Deaths among older registrants and the continuing influx of younger registrants offset aging among continuing registrants (see figure 2 on the website). The mean age of newly diagnosed cases remained comparatively constant after the first 4 years once the register captured an initially unrecognized group of untreated patients with type 2 diabetes and those who had been treated through diet, as well as people who did not regularly purchase drugs from the organization. The age of newly enrolled members who already had diabetes fell steadily. The mean age of those on the register who died increased from 73.1 (0.69) years to 75.8 (0.52).

Changes in comorbidity at diagnosis

Registrants entering in 1987 are excluded from the Chronic Disease Scores data for that year because electronic data for 1986 were incomplete. There was a comparatively constant level of chronic illness at the time of diagnosis for the first 6 years of the register, followed by a downward shift to less severe comorbidity in 1993 and a year of particularly less severe comorbidity in 1994 (see table 1 on the website).

Preventive health measures

The rates of annual influenza immunizations and screening for retinopathy remained unchanged until 1994 and

1995, when formal outreach systems began (see figure 3 on the website). The annual rate of retinal screening increased from 50% (5,926/11,758) (SE ± 0.5%) to almost 68% (±0.4%) within 2 years. The proportion of registrants receiving immunizations grew from 40% (4,045/10,037) to 60% (7,886/13,099) over 4 years, as reminders were mailed to all registrants and special flu clinics were established.

Rates of annual testing for diabetes control (total glycohemoglobin, HbA_{1c}, or fructosamine) and nephropathy screening both rose between 1987 and 1996 (see figure 4 on the website). Rates of testing for glycemic control increased from about 22% (1167/5331) (±1.9%) to over 83% (10,885/13,099) (±0.3%). Rates of nephropathy screening increased from 1% (±0.5%) to 43% (5,698/13,099) (±0.4%). Annual rates of testing for lipid concentration, (37% [1994/5331] ±2.2% in 1987) increased to 56% (7,332/13,099) (±0.4%) by 1996.

Use of pharmaceuticals

Both home glucose testing and pharmaceutical treatment for hyperlipidemia increased substantially over the decade. Hyperlipidemia treatment among members without diabetes also grew but not as rapidly. The proportion of members on the diabetes register who purchased antihypertensive drugs was high initially (57% [3060/5331]; ±7%) and did not grow for registrants or members without diabetes. However, the use of angiotensin converting enzyme inhibitors grew among members with diabetes from 8.5% (453/5331) (±0.4%) to 34.8% (4558/13,099) (±0.4%), while treatment with thiazide diuretics declined. The use of angiotensin converting enzyme inhibitors also grew among those without diabetes but much less quickly (see table 2 on the website).

Shifts in antihyperglycemic purchasing also occurred. Sulfonylurea and insulin use declined somewhat among all registrants and among new members who had previously been diagnosed with diabetes. Among newly diagnosed members, insulin use dropped substantially after 1987 and then more gradually after about 1991. Metformin was quickly adopted when it became available in 1995, primarily as a second agent used in conjunction with a sulfonylurea and primarily among registrants whose disease was of longer duration.

Control of risk factors

Total cholesterol concentrations improved over the decade from a mean of 243 (±4.2) mg/dL in 1987 to 215 (±0.55) mg/dL in 1996 (see figure 5 on the website). By 1996, mean HbA_{1c} concentrations among members with diabetes had dropped to almost 8.0% (±0.02%). The proportion of members on the register in very good or excellent control of their diabetes (HbA_{1c} <8.0%) reached 56.4% (±0.5%). The blood pressure of members on the register fell from 144/82 mm Hg (± 0.81/0.43) in 1987 to 138/79 mm Hg (±0.28/0.15) in 1996 (see table 3 on the website).

Utilization of medical services

The rate of visits to the organization's emergency room fluctuated as data systems, definitions of visits, and clinic hours changed over the decade (see figure 6 on the website). Rates of emergency room visits by members with diabetes, however, dropped steadily compared with those of members without diabetes. The number of days of acute hospitalization also decreased more for members with diabetes than for members without diabetes, causing the ratio of hospital days for members with diabetes to those without to fall from 3.6 in 1987 to 2.5 in 1996 (see figure 7 on the website). The total number of outpatient visits for members with diabetes increased slightly to about 13 per year, as visits to specialists increased faster than primary care visits decreased (see figure 8 on the website). The ratio of annual visits for members with diabetes to annual visits for those without also grew slightly, ranging from 1.71 to 1.87.

For members with diabetes, mortality declined from 4.8% (±0.3%) to 3.6% (±0.2%) per year. For members without diabetes, mortality did not change. A univariate linear regression of the ratio of mortality among members with diabetes to those without plotted against time indicated that there was a significant relative improvement in mortality among members with diabetes (adjusted R^2=0.50, β=–0.05, P=0.01).

DISCUSSION

Clinical trials have shown that intensified preventive care can improve the prospects of people with diabetes.[1-3, 5] Disease management programs that incorporate these findings into routine practice are widespread, but published evaluations have been short-term and generally have not measured mortality or other final outcomes.[20-24] In this report, we describe the changes that accompanied the implementation over 10 years of a chronic disease management program for diabetes mellitus in a large nonprofit, group-model health maintenance organization.

The steady growth of the diabetes register of the organization parallels national growth trends in the prevalence of diabetes that has persisted since the 1930s.[27] The relative contributions of more effective screening, weight gain in the population, and other factors cannot be determined from our data. However, the decline over time in the chronic disease score suggests a major role for better screening, a phenomenon that has also been observed nationally.[28]

Data show sustained improvement over 10 years in processes of care, such as rates of glycemic monitoring and retinal screening, improvements in biologic risk factors (glycemia, blood pressure, and hyperlipidemia), and a relative reduction in mortality, compared to a matched control population of members without diabetes. These favorable clinical outcomes were accompanied by a reduction, relative to members without diabetes, in the use of services that are resource intensive (such as emergency room and acute hospital care) without a drop in the use of outpatient care. When considered along with other studies that show the efficacy of similar quality-improvement methods in lowering diabetic risk factors,[15-19] generally poor processes of care and risk factor levels in the community,[29-31] and the efficacy of risk-factor reduction in preventing diabetic complications,[1-3,5] they also suggest that Kaiser Permanente's quality improvement program accounts for much of the observed reduction in risk factors, hospitalization, mortality, and usage of emergency services. This supposition cannot be proved by observational data, however. Because the randomized clinical trial method is not feasible for multimodal, continually evolving institutional programs such as that of Kaiser Permanente North West, such proof may never be forthcoming for programs of this kind.

To help clarify whether observed changes resulted from the implementation of the Kaiser Permanente program, we focused our analysis on performance ratios—measurements for members with diabetes divided by measurements for matched members without diabetes. These ratios show that rates of hospitalization, use of the emergency department, and mortality dropped more rapidly among people with diabetes than among other members of the health plan; they also rule out changes in the age-sex mix of the diabetes registry as explanations for these trends.

The role of the Kaiser Permanente program in producing these results remains confounded, however, by at least three other forces. Decreasing illness levels among entrants to the registry (probably due to earlier recognition of diabetes[28]) and general improvement in diabetes care (stimulated by clinical leaders, advocates, and research publications) imply an overestimation of the influence of the Kaiser Permanente program. Contemporaneous improvement in the care of Kaiser Permanente members without diabetes, which undoubtedly occurred and would have reduced the apparent treatment effect, implies an underestimation. The net effect is unknown. At a minimum, however, our results do not rule out the hypothesis that the efforts of the health maintenance organization to improve quality decreased the use of the hospital and emergency department as well as the mortality rate.

Our observational data also do not permit us to infer which aspects of the evolving program were most powerful. Although formal outreach programs had obvious, dramatic effects on rates of retinal screening and immunization, our descriptive approach cannot tease out, for example, the roles of influenza vaccination, glucose control, and lipid management in reducing mortality and hospitalization. Experimentally controlled trials are necessary to address this kind of question.

We do not report on such an experiment, although it is our experience that effective quality improvement efforts make use of all, and any, avenues available in a given setting. In the course of implementation, synergies arise, including considerable momentum around the quality improvement effort, which in itself motivates attentiveness and change. Implementation theorists advocate just this sort of approach that is directed from within the program and takes advantage of multiple models and channels.[32,33] Evaluating the frontiers of quality improvement in diabetes care in the real world must include the study of a program that is broadly evolving, mutually interacting, and non-research controlled, but largely evidence-based.

The quality improvement approach undertaken in our study site is not necessarily superior to other possible approaches. Kaiser Permanente itself has been incompletely satisfied, and has embraced other opportunities for improvement , such as a new electronic medical record system and an agreement to link compensation to the achievement of quality-of-care goals. By late 1999, the mean HbA_{1c} in the Kaiser Permanente Northwest registry had dropped to 7.75%, and programs were in place to increase the use of aspirin prophylactically and of antihyperlipidemic agents during 2000.

We did not attempt to measure all the costs and savings associated with this program. Nevertheless, the savings on acute inpatient care that can be extrapolated from our results are equivalent to roughly 4000 days of acute care avoided per 1000 registrants over 10 years. This represents a substantial benefit for people with diabetes and purchasers of health insurance, as well as for the health maintenance organization. A formal estimate of net economic impact would compare these and other savings to direct program costs and to program-stimulated cost increases, such as the costs of increased rates of drug treatment, substitution of more expensive drugs such as statins and angiotensin converting enzyme inhibitors, and more frequent laboratory monitoring. Simulation modeling thus far suggests that the intensification of care will increase the net costs of medical care.[34-37]

CONCLUSION

We have studied processes of care, patterns of resource utilization, and clinical outcomes over 10 years in a large population-based cohort of members with diabetes. We observed progressive improvement in all areas, consistent

with the hypothesis that better organization and delivery of diabetes care will improve both clinical behavior and clinical outcomes in the long term.

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